IS 11302-1 (1985): Electro-encephalograph (EEG), Part 1: General and Safety Requirements [MHD 19: Immuno-Biological Diagnostic Kits]

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Indian Standard

SPECIFICATION FOR ELECTRO-ENCEPHALOGRAPH (EEG)

PART 1 GENERAL AND SAFETY REQUIREMENTS

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SPECIFICATION FOR ELECTRO-ENCEPHALOGRAPH (EEG)

PART 1 GENERAL AND SAFETY REQUIREMENTS

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Indian Standard

SPECIFICATION FOR ELECTRO-ENCEPHALOGRAPH (EEG)

PART 1 GENERAL AND SAFETY REQUIREMENTS

0. FOREWORD

0.1 This Indian Standard (Part 1) was adopted by the Indian Standards Institution on 14 May 1985, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Electrotechnical Division Council.

0.2 The recording of the electrical activity of the brain is quite useful for the detection of abnormalities. The electro-encephalograph, popularly known as EEG, monitors the electrical activity of the brain for clinical diagnosis of brain disorders.

0.3 This standard (Part 1) specifies the general and safety requirements of EEG and Part 2 specifies performance requirements of EEG.

0.4 Legend of symbols of figures is given in Appendix A.

0.5 In preparation of this standard assistance was derived from IEC Pub 62D (Secretariat) 32 'Medical electrical equipment, electro-encephalograph: Part 2 Particular requirements for safety' issued by International Electrotechnical Commission.

0.6 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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1. SCOPE

1.1 This standard (Part 1) specifies general and safety requirements for electro-encephalographs and their associated accessories, intended for the

*Rules for rounding off numerical values (*revised*).

production of detachable graphic recording of electrical activity of the brain for diagnostic purposes.

1.2 Special requirements concerning other requirements in electro-encephalography (phono-photic stimulators), EEG telemetry, EEG data storage and retrieval, EEG monitoring of the critically ill, etc, are not covered by this standard.

2. TERMINOLOGY AND DEFINITIONS

2.0 For the purpose of this standard following terms, in addition to those defined in IS : 1885 (Part 43)-1977* shall apply.

2.1 Equipment, Parts, Accessories

2.1.1 *Channel* — Complete system for the detection, amplification and recording of potential differences between a pair or combination of electrodes.

2.1.2 *Electro-encephalograph (EEG)* — Electromedical equipment intended for the production of detachable graphic recordings of electrical activity of the brain for diagnostic purposes.

2.1.3 *Electro-encephalogram* — Detachable graphic recording of electrical activity of the brain.

2.1.4 *EEG Electrode* — Electrode applied over or inserted into a region of the scalp or brain to detect electrical activity of the brain in combination with another electrode or electrodes.

2.1.5 *Electrode Pre-amplifier* — Amplifier preceding on any input selector or montage selector.

2.1.6 *Electrode Lead* — Wire connecting an electrode to the electrode lead terminal (not applicable if the electrode is built together with a pre-amplifier).

2.1.7 *Electrode Lead Terminal* — Terminal on the electrode lead terminal box to which the electrode lead is connected.

2.1.8 *Etectrode Lead Terminal Box* — Arrangement for connection of the electrode leads.

2.1.9 *Filter* — Frequency selective circuit intended to an attenuate unwanted signals.

*Electrotechnical vocabulary: Part 43 Electrical equipment used in medical practice.

2.1.10 *Input Selector* — An arrangment for connecting the EEG electrodes or the electrode pre-amplifiers to the input terminals 1 and 2 of the channel amplifiers.

2.1.11 *Input Terminals* 1 — Input terminal of the channel amplifier at which negativity, relative to the other input terminal, produces an upward deflection. In diagrams, the connection of an electrode to the input terminal 1 of the channel amplifier is represented as a solid line.

2.1.11.1 *Input terminal* 2 — Input terminal of the channel amplifier at which negativity, relative to the other input terminal, produces a downward deflection. In diagrams, the connection of an electrode to the input terminal 2 of the channel amplifier is represented as a dotted or dashed line.

2.1.12 *Montage* — Particular arrangement by which a number of derivations are displayed simultaneously in an EEG record.

2.1.12.1 *Montage selector* — Switch arrangement to provide a montage.

2.1.13 *Neutral Electrode* — Electrode used as a common mode reference for differential amplifiers and/or interference-suppression. Not involved in EEG electrode combination.

2.2 Circuit-parameters

2.2.1 *Average Potential Reference* — Average of the potentials of all or a selection of EEG electrodes used as a reference.

2.2.2 *Calibration* — Facility enabling the calibration voltage or zero voltage to be recorder in place of EEG single.

2.2.3 *Calibration Voltage* — Voltage step recorded for amplitude calibration purpose.

2.2.4 *Common Mode Rejection* — A figure of merit to devote to the electro-encephalograph including the electrode leads, electrode dead terminal, patient cable, high frequency filters, protection networks, input selectors, amplifier input, etc, to attenuate common mode signals including EEG electrode impedance imbalance.

2.2.5 *Common Mode dc Offset Voltage* — Average component of dc voltage appearing of electrodes with respect to the neutral electrode.

2.2.6 *Common Mode Signal* — Common component of the two signals applied to the two respective input terminals of a differential EEG amplifier.

2.2.7 *Derivation*

2.2.7.1 The process of recording from a pair or a combination of electrodes in an EEG channel.

2.2.7.2 The EEG record obtained by this process.

2.2.8 *Differential Offset Voltage* — dc voltage appearing between EEG electrodes.

2.2.9 *Effective Recording Width* — Width of the recording paper within which the signal of a channel can be recorded according to this part of the standard and identical with the width determined by limits in the recording system.

2.2.10 *Electrical Interference* — External interference by changing electric fields.

2.2.11 *External Interference* — Unwanted disturbances in the recording produced by sources other than the patient.

2.2.12 *High Frequency Interference* — External interference produced by the operation of sources of radio frequency energy.

NOTE — Although the operating frequencies of such equipment may be outside the pass band of the EEG amplifier, because of non-lincarities in the system any modulation present on the rf signal, for example, 50 Hz, may be detected with resulting interference to the desired signal.

2.2.13 *Magnetic Interference* — External interference produced by the alternating magnetic field associated with conductors or equipment energized at power supply or other frequencies.

2.2.14 *Overload Tolerance* — Differential input-circuit voltage tolerated without resultant damage to the electro-encephalograph.

2.2.15 *Sensitivity* — Ratio of the amplitude of the input signal in μV to the amplitute of the resulting recording in mm expressed in μV/mm.

2.2.16 *Time Constant* — The time taken for the recorded output waveform in response to a dc step input step to decay to 36·8 percent of the initial amplitute.

(This definition is only valid if the system is equipped with a first order filter network).

2.2.17 *Neutral Etectrode* — Electrode used as a common mode reference for differential amplifiers and/or suppression. Not involved in EEG electrode combination. (Also referred to as ground electrode.)

3. CONSTRUCTION AND GENERAL REQUIREMENTS

3.1 Electro-encephalograph shall be so designed and constructed that it meets the safety and performance requirements. It shall be finished externally to withstand normal handling. Attention shall be given to the layout of the controls and their labelling to provide effortless operation over long period with minimum error. Construction of the equipment shall conform to IS : 8607 (Part 7)-1985*.

3.2 The electrode lead to equipment connector of type BF and CF equipment shall, when separated from the equipment have no conductive patient connected parts which are capable of contact with a flat conductive surface of not less than 100 mm diameter.

Compliance shall be checked by inspection and measurement.

3.3 Main Terminal Devices and Wiring — Soldering or clamping of requirable non-detachable supply cables or cords is allowed.

3.4 Creepage Distances and Air Clearances — The creepage distances and air clearances shall be as given in IS : 8607 (Part 7)-1985*.

4. GENERAL REQUIREMENTS FOR TESTS

4.1 The provisions of **5** of IS : 8607 (Part 1)-1977† shall apply except as specified in **5.2**.

4.2 Tests for protection against the effects of a cardiac defibrillator discharge shall be carried out prior to the leakage current and dielectric strength test as given in **5.3** of IS : 8607 (Part 1)-1977†.

5. CLASSIFICATION

5.1 The relevant provisions of **6** of IS : 8607 (Part 1)-1977† shall apply except 'Class III equipment' shall not apply.

6. MARKING AND IDENTIFICATION OF DOCUMENTS

6.1 Marking on the Outside of Equipment

6.1.1 In addition to the provisions of **7.1** to **7.2** of IS : 8607 (Part 1)-1977*, the requirements specified in **6.1.2** and **6.1.3** shall apply.

*General and safety requirements for electrical equipment used in medical practice: Part 7 Construction.

†General and safety requirements for electrical equipment used in medical practice: Part 1 General.

6.1.2 If applicable marking on the panel that the electro-encephalograph is protected against the effects of defibrillation discharge (*see* **9.4.3** and Appendix A).

6.1.3 *Instructions for Use* — The instructions for use shall additionally contain the following:

a) Advice on the procedures necessary for safe operation drawing attention in the case of type B electro-encephalographs to the safety hazards, which may occur as a result of an inadequate electrical installation;

b) Advice that conductive parts of electrodes and their connectors, including the neutral electrode, for type BF and CF electro-encephalographs should not contact other conductive parts including earth;

c) Advice on the type of electrical installation to which the equipment may be safely connected, including the connection of any potential equalization conductor;

d) The specification (or type-number) of the patient cable to meet any defibrillation protection and protection against high frequency burns (*see* **9.2.3**);

e) If the electro-encephalograph is provided with protective means against burns when used with HF surgical equipment such means shall be described;

f) Advice on the possible hazard caused by the summation of leakage currents when several equipments are interconnected;

g) Instructions for regular testing of the electro-encephalograph and the patient cable;

h) Where relevant a statement that the electro-encephalograph is protected against the effects of a cardiac defibrillator discharge (*see* **9.2.3**); and

j) Advice on the precautions to be taken when a defibrillator is used on a patient.

6.1.4 *Technical Description* — The manufacturer shall explain, if applicable, why the power supply cord of a class II equipment has three conductors (*see* **9.5.2**).

7. POWER INPUT

7.1 The relevant provisions of IS : 8607 (Part 1)-1977* shall apply.

8. SAFETY REQUIREMENTS

8.1 The relevant provisions of IS : 8607 (Part 1)-1977* shall apply.

9. PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

9.1 Requirement Related to Classification

9.1.1 The relevant provisions specified in **4** of IS : 8607 (Part 2)-1978† shall apply.

9.2 Insulation and Protective Impedances

9.2.1 The relevant provisions of **7** of IS : 8607 (Part 2)-1978† shall apply with additional requirements specified in **9.2.2.**

9.2.2 Any accessible conductive parts of type BF or CF equipment shall be so isolated from the applied part that the relevant patient leakage current requirements are met during the following test.

NOTE — Compliance shall be checked by connection of the accessible conductive parts to earth during the test of **9.3.13** of IS : 8607 (Part 2)-1978† (main voltage on the applied part) measurement of the resultant patient leakage current (*see* Fig. 1). Excluded are the surface of the EEG electrodes.

9.2.3 *Protection Against the Effects of a Cardiac Defibrillator Discharge*

9.2.3.1 Where means are incorporated for protection against the effects of the discharge of a cardiac defibrillator, arrangements used to isolate any electro-encephalographs electrode from parts mentioned below (a), (b), (c) and (d) shall be so designed that during the discharge of a defibrillator to a patient connected to the electro-encephalographs electrodes hazardous electrical energies are excluded from the following:

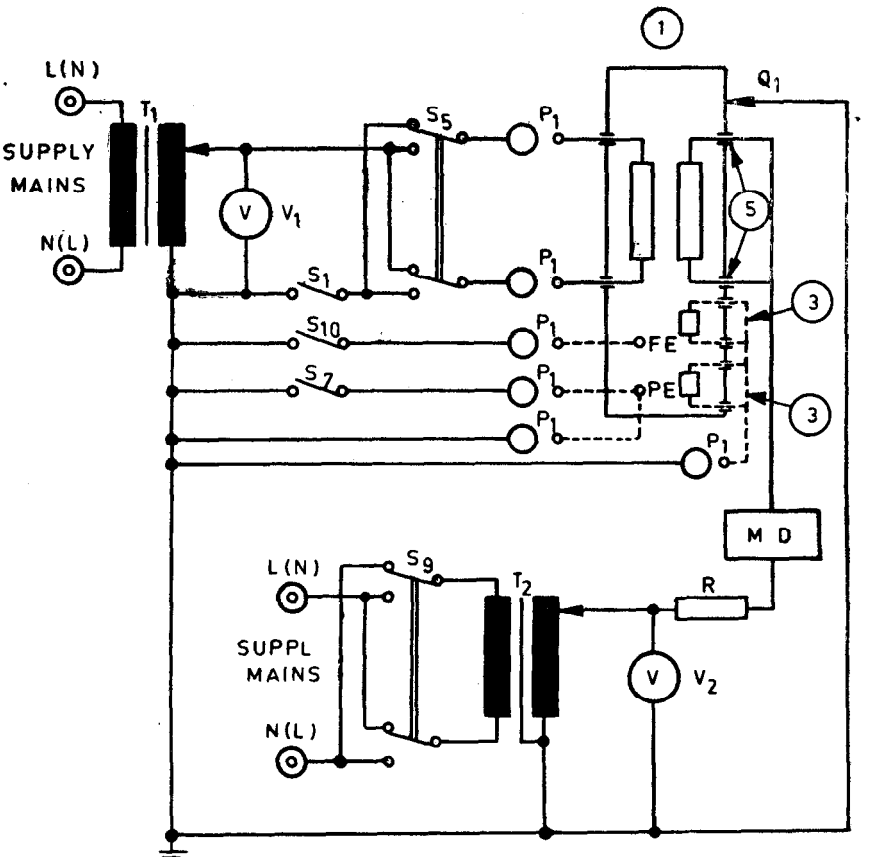
a) The body of the euipment;

b) Any signal input part;

c) Any signal output part; and

*General and safety requirements for electrical equipment used in medical practice: Part 1 General.

†General and safety requirements for electrical equipment used in medical practice: Part 2 Protection against shock.



Measure (with S_7 closed. If Class 1) with S_1 closed under all possible combinations of positions of S_5 and S_9 and of S_{10} . (when present) (Single Fault Condition).

FIG. 1 MEASURING CIRCUIT FOR THE PATIENT LEAKAGE CURRENT VIA AN *F*-TYPE ISOLATED (FLOATING) APPLIED PART TO EARTH OF CLASS I EQUIPMENT CAUSED BY AN EXTERNAL VOLTAGE ON THE APPLIED PART. FOR CLASS II EQUIPMENT, THE PROTECTIVE EARTH CONNECTION (S) AND S ARE NOT USED. IF AVAILABLE, ACCESSIBLE CONDUCTIVE PARTS SHALL BE CONNECTED TO EARTH BY MEANS OF Q_1.

d) Metal foil on which the equipment is placed and which has an area at least equal to the base of the equipment (Class II equipment or internally powered equipment).

NOTE — The above requirement is met when after operation of S_1 (*see* Fig. 2) the peak voltage between the points Y_1 and Y_2 do not exceed 1 V. The equipment shall not be energized.

Class I equipment shall be tested while connected to the protective earth.

Class I equipment which is capable of operation without a supply mains, for example, having an internal battery, shall also be tested without the protective earth connection. Any connection to a functional earth shall be removed.

Repeat the test with VI reversed.

9.2.3.2 Where means are incorporated for protection against the effects of the discharge of a cardiac defibrillator, the electro-encephalograph shall be tested by connection to the test circuit of Fig. 3.

NOTE — Compliance shall be checked by inspection and carrying out the following test, with an arbitrary electro-encephalograph electrode and an arbitrary channel connected to P_1 and P_2 of Fig. 3.

The electro-encephalograph operated normally shall be connected to as shown in Fig. 3.

With the capacitor charged to the source voltage and S_2 closed, S_1 is operated in position B for a period of 200 ms $\pm$ 50 percent. Repeat the test with the polarity of the source voltage reversed.

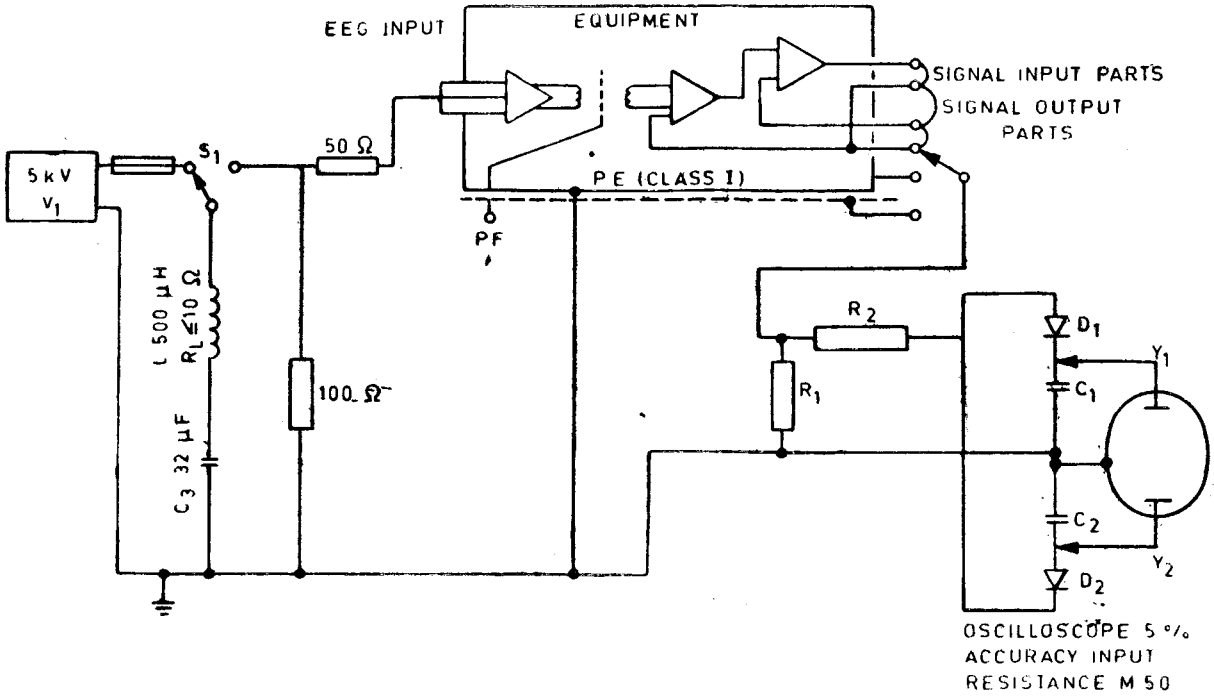
It is necessary to disconnect the capacitor in order to remove residual voltages from the electro-encephalograph to allow recovery to commence.

After the restoration of S_1 to position, the electro-encephalograph shall meet all requirements of this standard (*see* also **4.2**).

9.3 Earthing and Potential Equalization

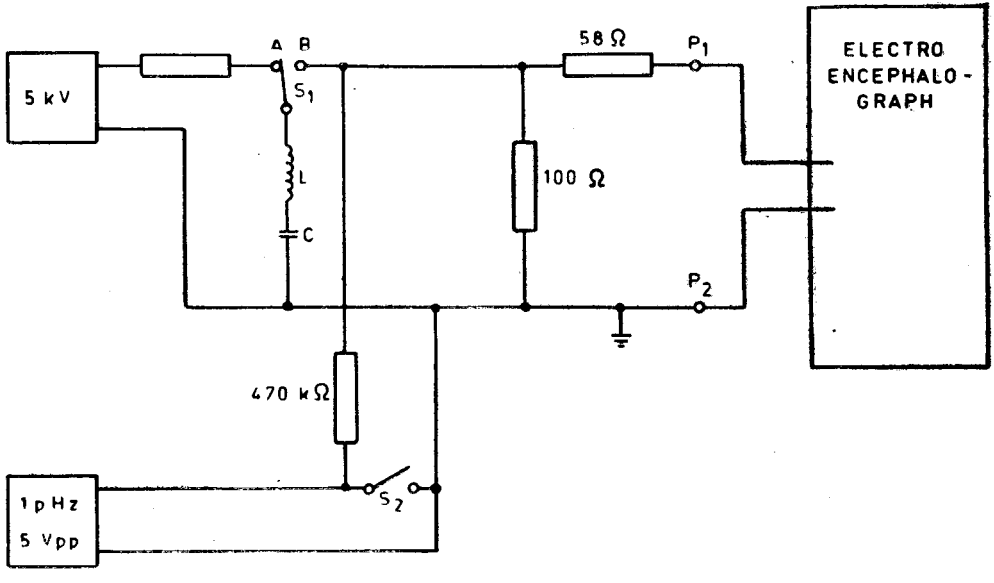
9.3.1 The relevant provisions of IS : 8607 (Part 2)-1978* shall apply.

*General and safety requirements for electrical equipment used in medical practice: Part 2 Protection against electric shock.



$R_1 = 1$ k Ω ± 2% } not less than
$R_2 = 100$ k Ω ± 2% } 2 kV rating
$C_1 = 1$ μ F ± 5%
$C_2 = 1$ μ F ± 5%
D_1 and D_2 small signal silicon drodes

FIG. 2 DYNAMIC TEST FOR LIMITATION OF ENERGY FROM DIFFERENT PARTS



$L = 500\ \mu H$ $R_L \leqslant 10\ \Omega$ $C = 32\ \mu F$

FIG. 3 TEST OF PROTECTION AGAINST THE EFFECTS OF DEFIBRILLATION

9.3.2 If Class II electro-encephalographs with isolated internal screens is supplied with a power supply cord having three conductors, the third conductor (connected to the protective earth contact of the mains plug) shall be used only as functional earth for these screens and coloured green/yellow.

NOTE — Compliance shall be checked by inspection and measurement.

9.4 Continuous Leakage Currents and Patient Auxiliary Currents

9.4.1 The relevant provisions of IS : 8607 (Part 2)-1978* shall apply with the modifications specified in **9.4.2**.

9.4.2 Equipment having a functional earth terminal shall limit the patient leakage current from the applied part to earth below the values given in Table 1 when a voltage equal to 110 percent of the highest rated mains voltage is applied between the functional earth terminal and earth.

This test shall not be performed when the functional earth terminal is connected directly to the protective earth terminal inside the equipment.

TABLE 1 PATIENT LEAKAGE CURRENT (MAINS VOLTAGE ON THE FUNCTIONAL EARTH TERMINAL)

TYPE OF EQUIPMENT OR APPLIED PART	ALLOWABLE VALUES (mA)
(1)	(2)
B, BF	5
CF	0, 05

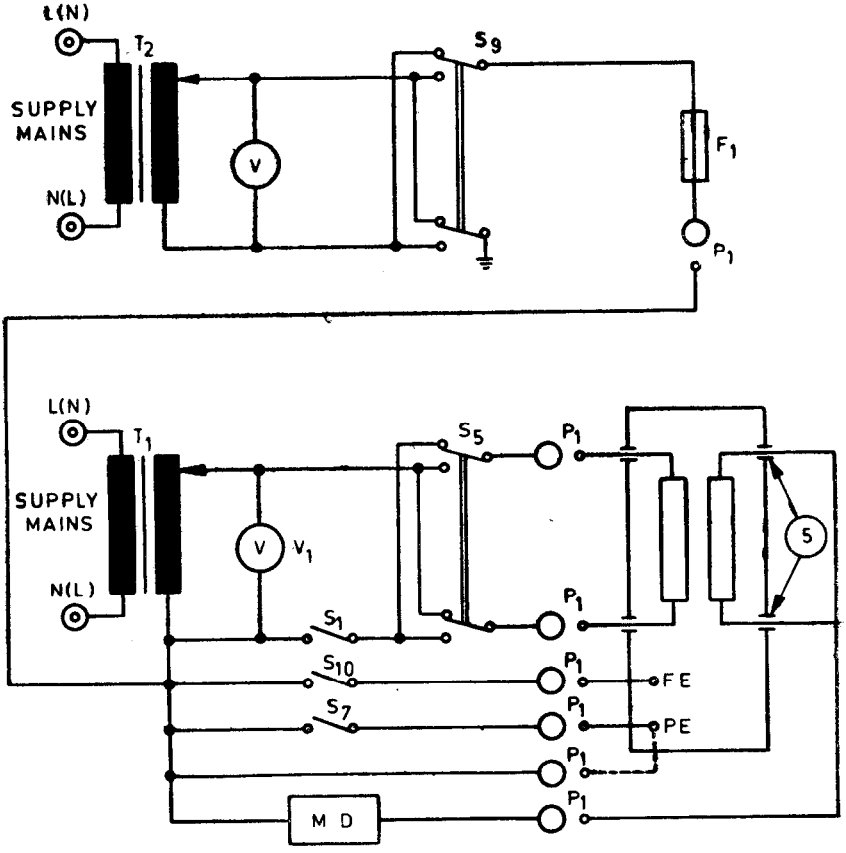
NOTE — Compliance shall be checked by measurement according to Fig. 4 and 5.

9.5 Dielectric Strength

9.5.1 The provisions of **10** of IS : 8607 (Part 2)-1978* shall apply with the modification of **9.2** as specified in **9.5.2**.

9.5.2 *Particular Requirements for Equipment with an Applied Part* — **9.2** (b) of IS : 8607 (Part 2)-1978* is not applicable for electro-encephalographs. Also for electro-encephalographs the requirements as specified in **9.2** (c) of IS : 8607 (Part 2)-1978* and test voltages apply as for **9.2** (d) of that standard.

*General and safety requirements for electrical equiqment used in medical practice: Part 2 Protection against electric shock.



Measure (with S_7 closed, if Class I) with S_1 closed under all possible combinations of positions of S_5 and S_9 and of S_{10} (when present) (Single Fault Condition).

FIG. 4 MEASURING CIRCUIT FOR THE PATIENT LEAKAGE CURRENT FROM THE APPLIED PART TO EARTH OF CLASS I EQUIPMENT CAUSED BY AN EXTERNAL VOLTAGE ON A FUNCTIONAL EARTH TERMINAL. FOR CLASS II EQUIPMENT THE PROTECTIVE EARTH CONNECTION (S) AND S_7 ARE NOT USED (*See* **9.4.2**).

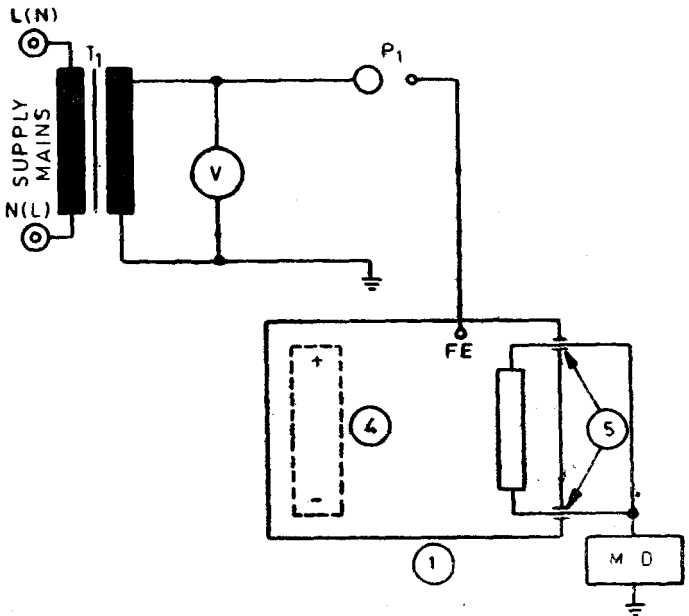


FIG. 5 MEASURING CIRCUIT FOR THE PATIENT LEAKAGE CURRENT FROM THE APPLIED PART TO EARTH OF EQUIPMENT WITH AN INTERNAL ELECTRICAL POWER SOURCE CAUSED BY AN EXTERNAL VOLTAGE ON A FUNCTIONAL EARTH TERMINAL

9.5.3 *Values of Test Voltages* — The relevant provisions of **9.3** of IS : 8607 (Part 2)-1978* shall apply.

9.5.4 For electro-encephalographs the test voltage shall not be less than 1 500 V, even if the reference voltage U is less than 250 V.

(Class I and II equipment and internally powered equipment.)

NOTE — Comments invited on the value of test voltage (1 500 V).

10. PROTECTION AGAINST MECHANICAL HAZARDS

10.1 The provisions of IS : 8607 (Part 3)-1979† shall apply.

*General and safety requirements for electrical equipment used in medical practice: Part 2 Protection against electric shock.

†General and safety requirements for electrical equipment used in medical practice: Part 3 Protection against mechanical hazards.

11. PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

11.1 The provisions of IS : 8607 (Part 4)-1985* shall apply except that when the recorder is equipped with an ultra-violet lamp, the electro-encephalograph should be so designed and constructed as to prevent the emission of ultraviolet emission of wavelength below 320 mm, to protect the patient and/or user.

12. PROTECTION AGAINST EXPLOSIVE HAZARDS

12.1 The provisions of IS : 8607 (Part 5)-1983† shall apply.

13. PROTECTION AGAINST EXCESSIVE TEMPERATURES, FIRE AND OTHER HAZARDS, SUCH AS HUMAN ERRORS

13.1 The relevant provisions of IS : 8607 (Part 6)-1984‡ shall apply except that provision of guard is not applicable to the heated stylus or printing element and requirement of spillage is not applicable for an electro-encephalograph.

14. ACCURACY OF OPERATING DATA AND PROTECTIONS AGAINST INCORRECT OUTPUT

14.1 Provision of IS : 8607 (Part 8)-1985§ shall apply.

APPENDIX A

(*Clause* 0.4)

LEGEND OF SYMBOLS FOR FIGURES

Legend of Symbols for Figures

1 —equipment

2 —specified power supply

3 —signal input or signal output part, short-circuited or loaded.

*General and safety requirements for electrical equipment used in medical practice: Part 4 Protection against unwanted or excessive radiation.

†General and safety requirements for electrical equipment used in medical practice: Part 5 Protection against explosive hazards medical treatment lamps.

‡General and safety requirements for electrical equipment used in medical practice: Part 6 Protection against excessive temperature air and other hazards.

§General and safety requirements for electrical equipment used in medical practice: Part 8 Behaviour and reliability.

4 —internal electrical power source

5 — applied part.

T_1, T_2 — single-, double-, polyphase isolation transformer with sufficient power rating and adjustable output voltage.

V (1, 2, 3) — voltmeter indicating rms value, if relevant possibly with one meter and commulator switch.

S_1, S_2, S_3 — single-pole switches, simulating the interruption of a power supply conductor (single fault condition).

S_5, S_9 — commulator switch to reverse the polarity of the mains voltage.

S_7, S_8 — single-pole switches, simulating the interruption of a single protective earth conductor (single fault condition).

S_{10}, S_{11} — switch for connecting a functional earth terminal (when present) to the earthed point of the measuring supply circuit.

S_{12} — switch for connecting an F-type isolated (floating) applied part (when present) to the earthed point of the measuring supply circuit.

P_1 — sockets, plugs or terminals for the connection of the equipment.

P_2 — sockets, plugs or terminals for the connection of a specified power supply.

R — impedance for portection of user of test apparatus:

for Type BF: 22 000Ω (120-130 V);
47 000Ω (220-240 V); and
for Type CF: 100 000Ω (220-240 V).

MD — measuring device.

FE — Functional earth terminal.

PE — Protective earth terminal.

F_1 — fuse of suitable rating to prevent damage to equipment.